How to Validation and Verification of Radiochemical Analytical Methods in the MIRACLE

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1. Introduction

In decommissioning of nuclear facilities, the radioactivity of various radionuclides has to be measured for estimation of the total inventory of radioactivity and its variation with time. The requirement for radionuclide characterization in support of nuclear decommissioning has resulted in a diverse range of material types requiring analysis. However, since there are many different types of nuclear waste from decommissioning activities, the reported methods do not cover all types of the waste, there are always requirement to develop new methods for different types of samples. For the characterization of waste, some radiochemical analytical methods have been developed for the determination of various radionuclides in some types of samples. To underpin data quality, they must confirm that the technique selected for analysis is fit for purpose and all techniques must be validated to confirm this. The validation process is designed to assess the performance of the technique in terms of analytical accuracy, precision, sensitivity and robustness and to compare these parameters with the required performance targets.

In this study, we are developing the new mobile radiochemical analytical methods called the "MIRACLE". Accordingly, an overview of how validation and verification in the MIRACLE is discussed.

2. Methods and Results

Results of analytical measurements have an extraordinarily great impact on practice. In radiochemical analysis, they can definitely and sometimes even fatally affect in the total inventory of radioactivity. It is the professional duty of radiochemical analysts to carry out measurements of sufficient quality. Validation and verification provide absolutely necessary data about uncertainty of the measurement results. Accreditation, which means official confirmation of a laboratory's competence the use of properly validated and verified measurements.

2.1 The MIRACLE

The MIRACLE is a mobile laboratory for radiochemical measurement and analysis. It will be consisted of α −spectrometry, γ -spectrometry, LSC, ICP-MS, wastes pre-treatment module, and volatile and non-volatile radionuclide separation modules.

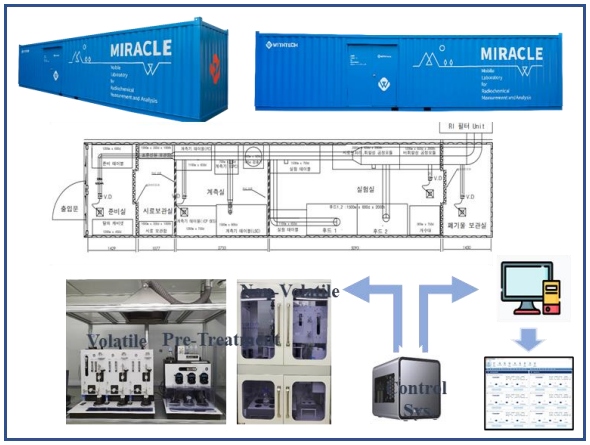

Fig. 1. Schematic Diagram of the MIRACLE

2.2 Validation & Verification

Validation is confirmation that the requirements for specifically intended use or specific applications were met through objective evidence. Verification means confirmation that the analytical characteristics data provided by a manufacturer, a laboratory or a reference institution were reached through objective evidence in the given laboratory with the use of a specific measuring system. Validation confirms that the measurement method/measuring system is capable of meeting the requirements set on it. In other words, it confirms that the level of measurement is sufficient, the measurement procedures are correct and the calibration was properly done. Verification means that the measurement method/measuring system is fully functional in a specific laboratory.

2.3 How to Validation & Verification

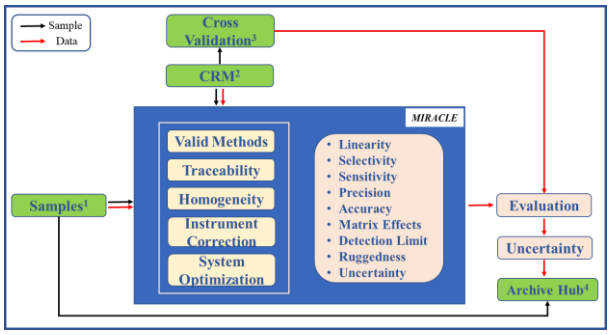

Fig. 2. The Flow Chart of the Validation & Verification Method for Radiochemical Analysis Results

The subject matter of this recommendation is validation and verification of measurement methods and measuring systems. The main aim of validation is to assess analytical and performance characteristics of methods and to make sure that the requested level of these characteristics was achieved. Extent and intensity of validation must always correspond with the need to get sufficient amount of data enabling to decide whether the method is really suitable for the intended purpose. Validation plans depend on the character of the validated method. The validation of a qualitative method requires much lesser effort, than the validation of a quantitative method.

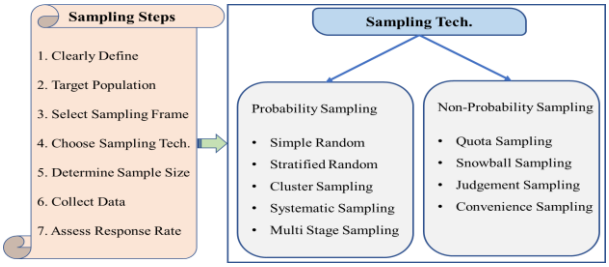

Fig. 3. The Representative Sampling Procedures

The factors closely related to validation and verification are as below.

- Purpose of measurement;
- Definition of the analyte;
- Sampling; sample transport and handling;
- Summary of minimal requirements of the measuring device quality
- Sequence of measurement standards;
- Calibration of measurement;
- Precision;
- Bias and recovery;
- Checking of the used calculations validity;

Table I: CRM of the Various Radiowastes

Items	Metal (Solution)	Soil (Low)	Soil (High)	Concrete (Low)	Concrete (High)
Matrix	Fe (13.72 g/kg) Ni (1.85 g/kg) Cr (3.8 g/kg) Mn (0.4 g/kg)			Cement(30%) SiO_2 (60%) Bentonite(10%)	Cement(30%) SiO_2 (60%) Bentonite(10%)
Radioisotope	Co-60 (2 Bq/kg) Sr-90 (20 Bq/kg) Cs-134 (2 Bq/g) Cs-137 (2 Bq/g)	Co-60 (0.1 Bq/g) Cs-137 (0.1 Bq/g)	Co-60 (1.0 Bq/g) Cs-137 (1.0 Bq/g)	Co-60 (0.1 Bq/g) Cs-137 (0.1 Bq/g)	Co-60 (1.0 Bq/g) Cs-137 (1.0 Bq/g)
Amounts	1 kg	100 kg	100 kg	100 kg	100 kg
Size, Θ	-	5~6 mm	5~6 mm	5~6 mm	5~6 mm
Manufacturer	KRISS	KRISS	KRISS	KRISS	KRISS

- Sensitivity, linearity, measuring interval, limit of detection/quantification;
- Robustness;
- Uncertainty of measurement;
- Determination of quality control limits;
- Recording of validation studies results;
- Validation/verification documents;
- Statement on the ability of the method to comply with the specified requirements;
- Comprehensive documentation of the quality control.

2.4 Archive Hub System

Eventually, all samples and data are stored in archive hub system for reanalysis and revalidation. The error of the radiochemical analysis results may be verified by reanalysis. it will be also shared to help people who need it most.

Fig. 4. Archive Hub Operation System for Reanalysis

3. Conclusions

The trend of modern analytical measurement is clear. Validated kits and measuring systems should be used and laboratories should concentrate mainly on assessments of measurements uncertainty, quality control, education, continuous observation of information, and implementation of new findings in practical laboratory activity.

The overview of how validation and verification in the MIRACLE was discussed for reliable results. There are lots of factors that closely related to validation and verification. Sampling, traceability, valid analytical method, uncertainty and archive were studied.

ACKNOWLEDGMENTS

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